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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,870	04/16/2004	Iddys D. Figueroa	200316700-1	8624

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EXAMINER	
CHANG, ROSIE YUH LOO	
ART UNIT	**PAPER NUMBER**
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,870	FIGUEROA ET AL.	
	Examiner	Art Unit	
	ROSIE YL CHANG	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *22-53 and 63-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 54-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/17/2007, 04/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 54-62, drawn to method for producing an oral medication, classified in class 427, subclass 2.13.

II. Claims 22-33, 63-68,71-79, drawn to body treating composition, classified in class 424, subclass 472.

III. Claims 34-53, 69-70, drawn to apparatus, classified in class 118, subclass 642.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made to practice another and materially different process such as mixing and compressing the pharmaceutical composition into a tablet dosage form.

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP §

806.05(e). In this case the apparatus as claimed can be used to practice another and materially different process such as coating a design on paper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with W. Haymond on 1/17/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-21, 54-62. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-33, 63-68, 34-53, 69-70 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 9,12, 21, 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation of "said ...jettable pharmaceutical product". Claim 1 only states a "jettable pharmaceutical solution", and thus claim 2 lacks a clear antecedent basis for this limitation in the claim, because a "product" is broader in scope than a "solution".

Claim 9 recites the limitation of "said structural materials". Only "a structural material" is recited in claim 1. There is insufficient antecedent basis for this limitation in the claim 9.

Claim 12 recites the limitation of "a specific antidote"; it is unclear as to what is encompassed by the term "a specificf antidote", and how this differs from" an antidote". The term "specific" does not appear to further limit or accurately describe the claimed aspect of the invention.

Claim 21 recites the limitation of "modify a release rate"; it is unclear as to what is encompassed by the term "modify". One skilled in the art would not be apprised of which structural material(s) or pharmaceutical solution(s) to utilize and how to utilize each, such that the release rate is somehow "modified".

Claim 55 recites the limitation of "varying a quantity of ...polymer". There is insufficient antecedent basis for this limitation in the claim 55. The "polymer" is not the composition being dispensed-it is the polymer based structural material", which may include many other compounds beside the polymer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,3,4,5,6,7,9,10,11-15,21, 54, 55, 56, 58, 59, 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US 6,962,715).

Lee et al. ('715) teach a method of producing pharmaceutical dosage on an ingestible sheet (col. 1, line 7-13), i.e. oral medication, which comprises dispensing or ejecting (col. 12, line 27-32) fluid drops of a barrier material, i.e. structure material, over the bioactive fluid, i.e. pharmaceutical solution, deposits on the ingestible sheet. The barrier material is an edible coating made from a suitable polymeric material (col. 12, line 39-1) such as a water-soluble polyoxyethylene or cellulose ether derivative.

Lee et al. ('715) teach the dispensing system (col.8, line 49-54, see fig. 2a) containing a heater to remove water and other solvents after deposition of the bioactive fluid on ingestible sheet. [redacted] Lee et al. ('715) teach (col. 12, line 33-34) the barrier

material acts to seal the bioactive fluid from environment, to provide various protective properties to the bioactive substance. Each dispensed fluid on the ingestible sheet is dried (col.8, line 49-54) with a heater to remove water or solvents to form distinctive layers, thus the barrier polymeric material coated on the ingestible sheet is inherently dried/cured after each coating. Lee et al. ('715) further teach alternating multiple layers of bioactive materials and multiple layers of barrier materials which can be deposited on the ingestible sheet to form a dosage (col. 13, line 26-31) and the alternating layers are dried prior to depositing another layer over, thus meeting the limitations of claim 1 and claim 54.

As for claims 2, 3, 4:

Lee et al. ('715) teach using a fluid ejection cartridge to dispense pharmaceuticals on an ingestible sheet (col.3, line 66-67). The fluid ejection cartridge, i.e. inkjet material dispenser, is a drop-on-demand type fluid dispenser (col. 4, line 5-7). Lee et al. ('715) further teach a thermally activated fluid ejection cartridge to dispense medications in the form of drops on an ingestible media. Other methods of activation such as piezoelectric and acoustic activation may also be used in the fluid ejection cartridge (col.4, line 1-5). The specific elements (col. 4, line 46-49) on drop-on-demand fluid ejection cartridges have been referred to in the publication "Inkjet Technology and Product Development Strategies, ch.4 of Torrey Pines Research 2000".

Lee et al. ('715) further teach (col. 9, line 55-58) the barrier proactive materials, i.e. structural material, are dispensed from a fluid ejection cartridge, i.e. inkjet material dispenser.

As for claims 6, 7, 21, 55:

Lee et al. ('715) teach alternating multiple layers of bioactive materials and multiple layers of barrier materials which can be deposited on the ingestible sheet to form a dosage (col. 13, line 26-31) and the alternating layers coating are dried prior to depositing another layer over as disclosed above.

The barrier material polymers would necessarily provide some degree of rate-limiting characteristic to the drug dosage form because it is a barrier between the drug and gastrointestinal fluid.

As for claim 9:

Lee et al. ('715) teach depositing (col.12, line 25-29) a plurality of selective quantities of the structural material, i.e. the barrier materials, onto discrete locations of a substrate. (see fig. 6a-d).

As for claims 10, 11, 12, 14,15, 58, 59:

Lee et al. ('715) teach (col. 6, line 22-25) the fluid ejection cartridge, i.e. inkjet material dispenser can reproducibly and accurately eject drops of bioactive fluid from the ejector heads, depending (col. 5, line 4-10) on the parameters of the fluid ejection cartridge such as the size and geometry of the fluid ejector and the size and geometry of the nozzle. The bioactive fluid taught by Lee et al. ('715) inherently is jettable.

Furthermore, Lee el al. teach (col. 4, line 21-24) the bioactive fluid includes any type of drug, medication, medicament, vitamin, antibiotics (col.5, line 15) while been designed to form a jettable solution and dispensed by the inkjet material dispenser accurately. Therefore, the bioactive fluid, i.e., pharmaceutical solution inherently comprises a component for adjusting viscosity, i.e. vehicle component, and solvent in order to modify the pharmaceutical solution property to be accurately jetted by the inkjet material dispenser.

Claims 1, 8, 10, 11, 14, 15, 16, 17, 18, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sturzenegger et al. (US 4,197,286).

Sturzenegger et al. ('286) teach a method for producing an oral medication (col.3, line 38-40), comprising dispensing a polymer (col. 10, line 5-10) composition, i.e. the structural material, on an appropriate substrate to form a web. The webs are then dried, e.g. in a forced-air oven; and then dispensing a jettable (col. 17, line 60) active ingredient, i.e. pharmaceutical solution (col. 17, line 42-44) is dispensed onto dried web, i.e. structural material.

As for claim 8:

Sturzenegger et al. ('286) further teach the film compositions, i.e. the structural materials include gelatin (col. 9, line 4) and hydroxypropyl methylcellulose (col. 9, line 14).

As for claims 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20:

Sturzenegger et al. ('286) teach (col. 17, line 42-55) the active ingredient may be deposited onto said film in the form of a solution, i.e. pharmaceutical solution. The liquid utilized for these operations can be water, an organic solvent, e.g. ethanol or a hydroalcoholic solvent. A preferred method of loading active ingredient in a liquid form onto a moving film/web is electrostatic jet spray deposition; therefore, the pharmaceutical solution taught by Sturzenegger et al. ('286) inherently is a jettable solution. The active ingredient includes antibiotics (col. 34, line 45) and estrogens (col. 34, line 41).

Sturzenegger et al. ('286) further teach (col. 18, line 54-57) mixing the polymers (col. 17, line 17-18) with the active substances in a liquid carrier to form the pharmaceutical solution. The polymer and liquid carrier in the pharmaceutical solution inherently is the vehicle component for the system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11,12,13,14, 15-20 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. ('715) in view of Von Corswant (US 6,602,511).

Lee et al. ('715) teach that which is disclosed above. Lee et al. teach forming a pharmaceutical solution by mixing a vehicle, solvent and drug to solution, thus having

the has desired viscosity property, such as jettable. Lee et al. ('715) is silent concerning the formulation of the vehicle since it is obviously that any specific formula would depend on the specific drug intended for dosage form.

Von Corswant ('511) teaches a method of forming non-toxic vehicles (col. 2, line 53) for administration of drugs such as Felodipine (col. 6, line 58) orally. Von Corswant ('511) teaches the vehicle including a solvent (col. 3, line 7), water (col.4, line 58) is configured to dissolve the oral drug and the solvent, water, is configured to partially dissolve the structural material, i.e. a sorbitol (col. 3, line 25). Von Corswant ('511) further teaches the solvent is configured to not dissolve the structural material, which may be an organic solvent such as ethanol (col.4, line 65). Additionally, the vehicle includes surfactants (col. 4, line 56). Since Lee et al. (715) teach a jettable vehicle component for drug solution, Von Corswant ('511) teaches a safe vehicle formulation for oral drug solution, Von Corswant ('511) would have reasonably suggested the formulations of vehicle for drug solution in the method of Lee et al. (715). It would have been obvious to one of ordinary skill in the art to use the vehicles of Von Corswant ('511) in the method of Lee et al. ('715) with the expectation of successful results, because Von Corswant ('511) teach a safe, non-toxic vehicle for oral drug dosage form.

Allowable Subject Matter

There is no allowable subject matter at this time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSIE YL CHANG whose telephone number is 571-272-6466. The examiner can normally be reached on MONDAY TO FRIDAY 7: 00AM TO 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIMOTHY MEEKS can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEITH HENDRICKS
PRIMARY EXAMINER